

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Khan et. al.

Serial No.: To be assigned

Filed: April 8, 2004

For: METHODS AND USES FOR
PORTEIN BREAKDOWN PRODUCTS

Examiner: To be assigned

Group Art Unit: To be assigned

Attorney Docket No.: 3077-6384US

NOTICE OF EXPRESS MAILING

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INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 or PTO/SB/08 be considered by the Examiner and made of record. Copies of the listed documents are enclosed pursuant to 37 C.F.R. § 1.98(a). Copies of U.S. patents are not being submitted pursuant to Pre-OG Notices <<http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/idswouscopies.htm>> (visited 9/15/2003). Copies of foreign patent documents and non-patent literature are enclosed pursuant to 37 C.F.R. § 1.98(a)(2).

In accordance with 37 C.F.R. § 1.97(g) and (h), filing of this Information Disclosure Statement is not to be construed as a representation that a search has been made or an admission that the information cited herein is, or is considered to be, material to patentability as defined in

37 C.F.R. § 1.56(b). Further, no representation is made by Applicants herein that no other possible material information as defined in 37 C.F.R. § 1.56(b) exists.

U.S. Patent Documents

<u>U.S. Patent No.</u>	<u>Publication Date</u>	<u>Patentee</u>
#US- 4,977,244	12-11-1990	Muchmore et al.
US- 5,380,668	01-10-1995	Herron
#US- 5,677,275	10-14-1997	Lunardi-Iskandar et al.
#US- 5,851,997	12-22-1998	Harris
#US- 5,877,148	03-02-1999	Lunardi-Iskandar et al.
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#US- 2003/0119720 A1	6-26-2003	Khan et al.
#US- 6,596,688 B1	07-22-2003	Gallo et al.
#US- 6,620,416 B1	09-16-2003	Gallo et al.
US- 2003/186244 A1	10-02-2003	Margus et al.

Foreign Patent Documents

<u>Document No.</u>	<u>Publication Date</u>	<u>Patentee</u>
#WO 99/59617	11-25-1999	Erasmus Universiteit

#WO 97/49721	12-31-1997	University of Maryland
#WO 01/10907 A2	02-15-2001	University of Maryland
#WO 01/11048 A2	02-15-2001	University of Maryland
#WO 01/72831	10-04-2001	Erasmus Universiteit
#2 706 772	12-30-1994	Vacsyn
#EP 1 138 692 A1	10/04/2001	Erasmus Universiteit Rotterdam
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#WO 98/35691	08-20-1998	Proscript, Inc.
#WO 02/085117	10-31-2002	Eisai Co., Ltd.
#DE 3715662	11-19-1987	The Wellcome Foundation Ltd.
#DE 19953339	05-17-2001	Goldham Pharma GmbH
#96/04008	02-15-1996	Government of the United States
#97/49373	12-31-1997	University of Maryland Biotechnology Institute
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#FRIEDLANDER, Tackling anthrax, *Nature*, November 8, 2001, pp. 160-61, Vol. 414.

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#TAK et al., NF-kappaB: a key role in inflammatory diseases, *J Clin Invest.*, 2001, pp. 7-11, Vol. 107.

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#TOVEY et al., Mucosal Cytokine Therapy: Marked Antiviral and Antitumor Activity, *J. Interferon Cytokine Res.*, 1999, pp. 911-21, Vol. 19.

#ALBINI, A., et al., "Old drugs as novel angiogenesis inhibitors: Preclinical studies with NAC, hCG, EGCG and somatostatin," 17 *CLINICAL & EXPERIMENTAL METASTASIS* 739 (1999).

#BLACKWELL, Timothy S., et al., "The Role of Nuclear Factor-kB in Cytokine Gene Regulation," 17 *AM. J. RESPIR. CELL MOL. BIOL.* 3-9 (1997).

#KELLER, S., et al., "Human Chorionic Gonadotropin (hCG) Is a Potent Angiogenic Factor for Uterine Endothelial Cells *in Vitro*," 20(5-6) PLACENTA, page A37 (July 1999).

#KHAN, Nisar A., et al., "Inhibition of Diabetes in NOD Mice by Human Pregnancy Factor," 62(12) HUMAN IMMUNOLOGY 1315-1323 (December 2001).

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#SLATER, Lewis M., et al., "Decreased Mortality of Murine Graft-Versus-Host Disease by Human Chorionic gonadotropin," 23(1) TRANSPLANTATION 103-104 (January 1977).

#WULCZYN, F. Gregory, et al., "The NF- κ B/Rel and I κ B gene families: mediators of immune response and inflammation," 74(12) J. MOL. MED. 749-769 (1996).

#YAMAMOTO, Y., et al., "Role of the NF- κ B Pathway in the Pathogenesis of Human Disease States," 1(3) CURRENT MOLECULAR MEDICINE 287-296 (July 2001).

#Pursuant to 37 C.F.R. § 1.98(d), copies of the previously identified patents are not being provided since they were previously cited by or submitted to the Office in the following prior application:

Serial No.: 10/753,510

Filed: January 7, 2004

For: IMMUNOREGULATORY COMPOSITIONS, which application is being relied upon for an earlier filing date under 35 U.S.C. § 120.

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56 & 1.175, Applicants offer hereby identifies the following listed copending applications naming the same inventor(s):

Attorney Docket No.: 3077-6384US

Attorney Docket No.: 2183-4618US
Serial No.: 09/716,777
Filing Date: 11/20/2000
Title: IMMUNOREGULATOR

Attorney Docket No.: 2183-4799US
Serial No.: 09/821,380
Filing Date: 3/29/2001
Title: IMMUNOREGULATOR

Attorney Docket No.: 2183-5223US
Serial No.: 10/028,075
Filing Date: 12/21/2001
Title: GENE REGULATOR

Attorney Docket No.: 2183-5222US
Serial No.: 10/029,206
Filing Date: 12/21/2001
Title: OLIGOPEPTIDE TREATMENT OF ANTHRAX

Attorney Docket No.: 2183-5526US
Serial No.: 10/262,522
Filing Date: 9/30/2002
Title: IMMUNOREGULATOR

Attorney Docket No.: 3077-5951US
Serial No.: 10/409,027
Filing Date: 4/8/2003
Title: TREATMENT OF TRANSPLANT SURVIVAL

Attorney Docket No.: 3077-5952US
Serial No.: 10/409,032
Filing Date: 4/8/2003
Title: TREATMENT OF TRAUMA

Attorney Docket No.: 3077-5953US
Serial No.: 10/409,630
Filing Date: 4/8/2003
Title: TREATMENT OF MULTIPLE SCLEROSIS

Attorney Docket No.: 3077-6384US

Attorney Docket No.: 3077-5957US
Serial No.: 10/409,642
Filing Date: 4/8/2003
Title: TREATMENT OF ISCHEMIC EVENTS

Attorney Docket No.: 3077-5958US
Serial No.: 10/409,654
Filing Date: 4/8/2003
Title: TREATMENT OF NEUROLOGICAL DISORDERS

Attorney Docket No.: 3077-5960US
Serial No.: 10/409,657
Filing Date: 4/8/2003
Title: STRATIFICATION

Attorney Docket No.: 3077-5956US
Serial No.: 10/409,659
Filing Date: 4/8/2003
Title: PEPTIDE COMPOSITIONS

Attorney Docket No.: 3077-5959US
Serial No.: 10/409,668
Filing Date: 4/8/2003
Title: ADMINISTRATION OF GENE-REGULATORY PEPTIDES

Attorney Docket No.: 3077-5955US
Serial No.: 10/409,671
Filing Date: 4/8/2003
Title: TREATMENT OF IATROGENIC DISEASE

Attorney Docket No.: 3077-5954US
Serial No.: 10/409,694
Filing Date: 4/8/2003
Title: TREATMENT OF BURNS

Attorney Docket No.: 3077-4618.1US
Serial No.: 10/678,995
Filing Date: 10/3/2003
Title: IMMUNOREGULATOR

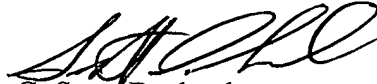
Attorney Docket No.: 3077-6384US

Attorney Docket No.: 3077-6084US
Serial No.: 10/753,510
Filing Date: 1/7/2004
Title: IMMUNOREGULATORY COMPOSITIONS

Attorney Docket No.: 3077-6420US
Serial No.: To be assigned
Filing Date: April 8, 2004
Title: COMPOSITIONS CAPABLE OF REDUCING ELEVATED
BLOOD UREA CONCENTRATION

This Information Disclosure Statement is filed within three (3) months of the filing date of the above-identified application, and no certification pursuant to 37 C.F.R. § 1.97(c) or a fee pursuant to 37 C.F.R. § 1.17(p) is required.

Respectfully submitted,



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Date: April 8, 2004
ACT/bv
Enclosures: Form PTO/SB/08

Document in ProLaw

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Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet

1

of

4

Complete if Known

Application Number	To be assigned
Filing Date	April 8, 2004
First Named Inventor	Khan et. al.
Group Art Unit	To be assigned
Examiner Name	To be assigned
Attorney Docket Number	3077-6420US

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
		#US- 4,977,244	12-11-1990	Muchmore et al.	
		US- 5,380,668	01-10-1995	Herron	
		#US- 5,677,275	10-14-1997	Lunardi-Iskandar et al.	
		#US- 5,851,997	12-22-1998	Harris	
		#US- 5,877,148	03-02-1999	Lunardi-Iskandar et al.	
		#US- 5,958,413	09-28-1999	Anagnostopoulos et al.	
		#US- 5,968,513	10-19-1999	Gallo et al.	
		#US- 5,997,871	12-07-1999	Gallo et al.	
		#US- 6,319,504	11-20-2001	Gallo et al.	
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		#US- 2002/0041871	04-11-2002	Brudnak	
		#US- 2002/0064501	05-30-2002	Khan et al.	
		#US- 6,489,296	12-03-2002	Grinnell et al.	
		#US- 2003/0049273 A1	03-13-2003	Gallo et al.	
		#US- 2003/0113733 A1	6-19-2003	Khan et al.	
		#US- 6,583,109 B1	06-24-2003	Gallo et al.	
		#US- 2003/0119720 A1	6-26-2003	Khan et al.	
		#US- 6,596,688 B1	07-22-2003	Gallo et al.	
		#US- 6,620,416 B1	09-16-2003	Gallo et al.	
		US- 2003/186244 A1	10-02-2003	Margus et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				
		#WO 99/59617	11-25-1999	Erasmus Universiteit		
		#WO 97/49721	12-31-1997	University of Maryland		
		#WO 01/10907 A2	02-15-2001	University of Maryland		
		#WO 01/11048 A2	02-15-2001	University of Maryland		
		#WO 01/72831	10-04-2001	Erasmus Universiteit		
		#2 706 772	12-30-1994	Vacsyn		
		#EP 1 138 692 A1	10/04/2001	Erasmus Universiteit Rotterdam		

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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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**INFORMATION DISCLOSURE
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Sheet 2 of 4

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Application Number	To be assigned
Filing Date	April 8, 2004
First Named Inventor	Khan et. al.
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U.S. PATENT DOCUMENTS

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		Number - Kind Code ² (if known)			
		US- 5,966,712	10-12-1999	Sabatini et al.	
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				April 8, 2004	

FOREIGN PATENT DOCUMENTS

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		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				
		#EP 1 300 418	04-09-2003	Erasmus Universiteit Rotterdam		
		#WO 98/35691	08-20-1998	Proscript, Inc.		
		#WO 02/085117	10-31-2002	Eisai Co., Ltd.		
		#DE 3715662	11-19-1987	The Wellcome Foundation Ltd.		
		#DE 19953339	05-17-2001	Goldham Pharma GmbH		
		#96/04008	02-15-1996	Government of the United States		
		#97/49373	12-31-1997	University of Maryland Biotechnology Institute		
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		#97/49432	12-31-1997	University of Maryland Biotechnology Institute		
		WO 03/029292 A2	04-10-2003	Erasmus Universiteit Rotterdam		

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¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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**INFORMATION DISCLOSURE
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Sheet 3 of 4

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Application Number	To be assigned
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First Named Inventor	Khan et. al.
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Examiner Name	To be assigned
Attorney Docket Number	3077-6420US

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		#CONNELLY et al., Biphase Regulation of NF-kB Activity Underlies the Pro- and Anti-Inflammatory Actions of Nitric Oxide, The Journal of Immunology, 2001, pp. 3873-81, 166, The American Association of Immunologists, USA.	
		#FRIEDLANDER, Tackling anthrax, Nature, November 8, 2001, pp. 160-61, Vol. 414.	
		#MEDZHITOV, Toll-like Receptors and Innate Immunity, Nature Reviews/Immunology, November 2001, pp. 135-45, Vol. 1.	
		#LANG et al., "Induction of apoptosis in Kaposi's sarcoma spindle cell cultures by the subunits of human chorionic gonadotropin", AIDS 1997, Vol. 11, No. 11, pp.1333-1340.	
		#ISKANDAR et al., "Effects of a urinary factor from women in early pregnancy on HIV-1. SIV and associated disease", Nature Medicine, April 1998, Vol. 4, No. 4, pp. 428-434.	
		#CHRISTMAN et al., Nuclear factor kappaB: a pivotal role in the systemic inflammatory response syndrome and new target for therapy, Intens Care Med, 1998, pp. 1131-38, Vol. 24.	
		#JYONOUCHI et al., Proinflammatory and regulatory cytokine production associated with innate and adaptive immune responses in children with autism spectrum disorders and developmental regression, J Neuroim., 2001, pp. 170-79, Vol. 120.	
		#KANUNGO et al., Advanced Maturation of Heteropneustes Fossilis (Bloch) by Oral Administration of Human Chorionic Gonadotropin, J. Adv. Zool., 1999, pp. 1-5, Vol. 20.	
		#ROHRIG et al., Growth-stimulating Influence of Human Chorionic Gonadotropin (hCG) on Plasmodium falciparum in vitro, Zentralblatt Bakt, 1999, pp. 89-99, Vol. 289.	
		#TAK et al., NF-kappaB: a key role in inflammatory diseases, J Clin Invest., 2001, pp. 7-11, Vol. 107.	
		#TAN et al., The role of activation of nuclear factor-kappa B of rat brain in the pathogenesis of experimental allergic encephalomyelitis, Acta Physiol Sinica, 2003, pp. 58-64, Vol. 55.	
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Sheet 4 of 4

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Filing Date	April 8, 2004
First Named Inventor	Khan et. al.
Group Art Unit	To be assigned
Examiner Name	To be assigned
Attorney Docket Number	3077-6420US

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		#ALBINI, A., et al., "Old drugs as novel angiogenesis inhibitors: Preclinical studies with NAC, hCG, EGCG and somatostatin," 17 CLINICAL & EXPERIMENTAL METASTASIS 739 (1999).	
		#BLACKWELL, Timothy S., et al., "The Role of Nuclear Factor-kB in Cytokine Gene Regulation," 17 AM. J. RESPIR. CELL MOL. BIOL. 3-9 (1997).	
		#KELLER, S., et al., "Human Chorionic Gonadotropin (hCG) Is a Potent Angiogenic Factor for Uterine Endothelial Cells <i>in Vitro</i> ," 20(5-6) PLACENTA, page A37 (July 1999).	
		#KHAN, Nisar A., et al., "Inhibition of Diabetes in NOD Mice by Human Pregnancy Factor," 62(12) HUMAN IMMUNOLOGY 1315-1323 (December 2001).	
		#KHAN, Nisar A., et al., "Inhibition of Septic Shock in Mice by an Oligopeptide From the β -Chain of Human Chorionic Gonadotrophin Hormone," 63(1) HUMAN IMMUNOLOGY 1-7 (January 2002).	
		#MUCHMORE et al., Immunoregulatory Properties of Fractions from Human Pregnancy Urine: Evidence that Human Chorionic Gonadotropin is not Responsible, The Journal of Immunology, March 1997, pp. 881-86, Vol. 118, No. 3.	
		#MUCHMORE et al., Purification and Characterization of a Mannose-Containing Disaccharide Obtained from Human Pregnancy Urine, Journal of Experimental Medicine, December 1984, pp. 1672-85, Volume 160.	
		#PATIL, A., et al., "The Study of the Effect of Human Chorionic Gonadotrophic (HCG) Hormone on the Survival of Adrenal Medulla Transplant in Brain. Preliminary Study," 87 ACTA NEUROCHIR (WIEN) 76-78 (1987).	
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Examiner
SignatureDate
Considered#Pursuant to 37 C.F.R. § 1.98(d), copies of the previously identified patents are not being provided since they were previously cited by or submitted to the Office in the following prior application:

Serial No.: 10/753,510

Filed: January 7, 2004

For: IMMUNOREGULATORY COMPOSITIONS, which application is being relied upon for an earlier filing date under 35 U.S.C. § 120.

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